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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/070,889 | 03/06/2002 | Minoru Takebe | 211A 3160 PCT | 2509 |
| <div>7590 Koda & Androlia Suite 1430 2029 Century Park East Los Angeles, CA 90067-3024</div> | | | <div>EXAMINER KIM, JENNIFER M</div> | |
| | | | <div>ART UNIT 1617</div> | <div>PAPER NUMBER.</div> |
| | | | <div>MAIL DATE 10/04/2007</div> | <div>DELIVERY MODE PAPER</div> |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/070,889 | Applicant(s) TAKEBE, MINORU | |
| | Examiner Jennifer Kim | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the Appeal Brief filed on June 18, 2007, PROSECUTION IS HEREBY REOPENED. A new grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1-5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Obata et al. (U.S. Patent No. 6,444,239 B2).

Obata et al. teach a product comprising 480g of isoflavone aglycone powder comprising an **isoflavone aglycone content of 52%**, which was found to be made up of 54% of genistein, 40% daidzein, and 6% of glycitein. (Example 3, column 5).

Accordingly, Applicant's recitation in claim 1 of an anti-obesity material has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of the same composition and such fail to impart any physical limitations beyond those possessed by the composition taught by the cited prior art.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being unpatentable by The Merck Index, tenth edition. (1983), (Merck).

Merck teaches that daidzein obtained from soybean. It is noted that the content of (pure) daidzein taught by prior art encompasses Applicant's amount set forth in claim 6.

Accordingly, Applicant's recitation in claim 1 of an anti-obesity material has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of the same composition and such fail to

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impart any physical limitations beyond those possessed by the composition taught by the cited prior art.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being unpatentable by Potter et al. (U.S. Patent No. 5,855,892).

Potter et al. teach pharmaceutical formulation of daidzein as an active agent. Potter et al. teach gelatin capsules comprising 10-1000mg of daidzein in a capsule and a tablet. Potter et al. also teach daidzein in 10-1000mg/5ml in a suspension. (column 7, under Formulations and formulations 1-3). These amounts of daidzein contained in the formulations overlap and encompasses Applicants' claimed amount of isoflavone aglycone at least 30%wt and at least 70wt% daidzein.

Accordingly, Applicant's recitation in claim 1 of an anti-obesity material has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of the same composition and such fail to impart any physical limitations beyond those possessed by the composition taught by the cited prior art.

Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Takebe et al. (U.S. Patent No. 5,885,632) of record.

Takebe et al. teach a food product prepared from a pulse crop (grains) as a starting material comprising fermentation to inhibit contaminants wherein the

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fermentation time depends upon the type of koji mold and a koji preparation comprising cooking pulse crop and hydrolyzing koji preparation by adding water comprising at least 70 wt% isoflavone aglycone (daizein) set forth in claims 1-5. (title, abstract, column 6, lines 48-49, column 7, lines 15-17, column 8 particularly, table 3, column 12, claims 7-10).

Applicant's recitation in claims 1-5 and 7 of an intended use of the material as being an anti-obesity material does not represent a patentable limitation since such fails to impart any physical limitation to the same composition taught by the prior art. Moreover, the oral supplement set forth in claim 7 would be inherent in the same composition taught by the prior art as being a food product.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of U.S. Patent No. 5,885,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because claims of the cited patent encompasses the instant claims. The claims of the present application and the cited patent are each drawn to a material comprising the product comprising isoflavone aglycone. Therefore, it would have been obvious to one of ordinary skill in the art to formulate the isoflavone aglycone composition comprising daizein as illustrated and taught in the patent. The intended use as an anti-obesity material in the instant claims does not represent a patentable limitation since such fails to impart any physical limitation to the same composition taught by the patent.

Claims 1-5 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,045,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because claims of the cited patent encompasses the instant claims. The claims of the present application and the cited patent are each drawn to a product comprising isoflavone aglycone. Therefore, it would have been obvious to one of ordinary skill in the art to formulate the

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isoflavone aglycone composition comprising daizein as illustrated and taught in the patent.

Claims 1-5 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-9 of U.S. Patent No. 6,303,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because claims of the cited patent encompasses the instant claims. The claims of the present application and the cited patent are each drawn to a product comprising isoflavone aglycone. Therefore, it would have been obvious that the product taught in the patent encompasses instant claims since the resulted component and the product is illustrated and taught in the specification on table 4, 5 comprising same isoflavone aglycone (daizein) with instantly claimed amounts.

Claims 1-5 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 5 of copending Application No. 10/533,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of cited co-pending Application encompasses the instant claims. The claims of the present application and the cited co-pending Application are each drawn to a product comprising isoflavone aglycone, daizein comprising at least 70% of daizein. Although the intended use differ

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because of the claims in the co-pending Application state that the product is intended for an anti-obesity material, however, the intended use does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the co-pending Application encompassing same active agent of daizein with same amounts drawn to a product claim. Therefore, the invention as claimed are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 and 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/507,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of cited co-pending Application encompasses the instant claims. The claims of the present application and the cited co-pending Application are each drawn to a product comprising isoflavone aglycone, daizein comprising at least 70% of daizein. Although the intended use differ because of the claims in the co-pending Application state that the product is intended for promoting biological activity which is broader since the promotion of biological activity encompasses prevention and treatment of a disease, however, the intended use does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the co-pending Application encompassing same

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active agent of daizein with same amounts drawn to a product claim. Therefore, the invention as claimed are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed June 18, 2007 have been fully considered but they are not persuasive. Applicants argue that the quantities of isoflavone aglycone produced in Takebe et al. are too small to have any anti-obesity effect. This is not found persuasive because the instant claims 1-5 and 7 do not require "therapeutic effective amounts" of isoflavone aglycone for the treatment of obesity but rather, any presence of isoflavone aglycone as a "material" as taught by the cited reference.

Applicants argue that Takebe et al. do not show or suggest concentration of the material to produce more isoflavone aglycone in the final product as set forth in claim 5. This is not found persuasive because it is well settled in patent law that product-by-process claims are not limited to the manipulations of the recited steps, only the structure

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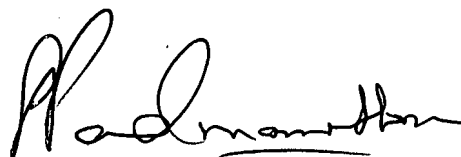
implied by the steps. See MPEP § 2123. The court in In re Thorpe held, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a horizontal line underneath the name.

Sreenivasan Padmanabhan
Supervisory Patent Examiner
Art Unit 1617

Jmk
September 27, 2007